

Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930, email: [elizabeth.giaquinto@fda.hhs.gov](mailto:elizabeth.giaquinto@fda.hhs.gov), or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “ANDA Submissions—Content and Format of Abbreviated New Drug Applications.” On July 9, 2012, the Generic Drug User Fee Amendments (GDUFA) was signed into law by the President to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. Under GDUFA, FDA agreed to certain obligations as laid out in the GDUFA Commitment Letter. Among these obligations is FDA’s commitment to performance metrics for the review of original ANDAs. For example, FDA has committed to review and act on 90 percent of original ANDA submissions within 10 months from the date of submission in Year 5 of the program, which begins on October 1, 2016.

In an effort to increase the number of original ANDAs that the Agency can receive upon initial submission and to decrease the number of review cycles required to approve an application for marketing, FDA prepared this guidance on improving the quality of original ANDA submissions. FDA is committed to providing comprehensive assistance in the early stages of the application process to ensure that an original ANDA

contains all information necessary for FDA to complete its review in one review cycle.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on “ANDA Submissions—Content and Format of Abbreviated New Drug Applications.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314.94 have been approved under 0910-0001. The collection of information in Form FDA 356h has been approved under 0910-0338. The collection of information for Form FDA 3674 has been approved under 0910-0616. The collection of information for Form FDA 3794 has been approved under 0910-0727. The collection of information for Form FDA 3454 has been approved under 0910-0393. The collection of information for Form FDA 3455 has been approved under 0910-0396. The collection information for 21 CFR part 11, Electronic Records, has been approved under 0910-0303.

##### **III. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

##### **IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/>

*GuidanceComplianceRegulatoryInformation/default.htm*, or <http://www.regulations.gov>.

Dated: June 5, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-13641 Filed 6-11-14; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2013-N-1504]**

#### **Independent Assessment of the Process for the Review of Device Submissions; Final Comprehensive Findings and Recommendations and First Implementation Plan; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice entitled “Independent Assessment of the Process for the Review of Device Submissions; Final Comprehensive Findings and Recommendations and First Implementation Plan” that appeared in the **Federal Register** of May 29, 2014 (79 FR 30853). The document announced Booz Allen Hamilton’s final comprehensive findings and recommendations submitted as part of their independent assessment of the process for the review of medical device submissions as well as FDA’s first implementation plan based on Booz Allen Hamilton’s high priority recommendations issued December 11, 2013. The notice was issued earlier than intended. The documents will be available on June 11, 2014, as required by the Medical Device User Fee Amendments of 2012 (MDUFA) III Performance Goals and Procedures Commitment Letter.

**FOR FURTHER INFORMATION CONTACT:** Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3291, Silver Spring, MD 20993-0002, 301-796-9384, [Amber.Sligar@fda.hhs.gov](mailto:Amber.Sligar@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Thursday, May 29, 2014, in FR Doc. 2014-12403, on pages 30853-30854, the following correction is made:

The notice implied that Booz Allen Hamilton’s final comprehensive findings and recommendations and FDA’s first implementation plan are available as of May 29, 2014. In fact, the

documents will be available Wednesday, June 11, 2014, at the following Web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm>.

Dated: June 6, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-13758 Filed 6-11-14; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2014-N-0001]**

#### **Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on July 30 and 31, 2014, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

*Contact Person:* Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring, MD 20993-0002, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to

learn about possible modifications before coming to the meeting.

*Agenda:* On July 30, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Ablatherm Integrated Imaging device sponsored by EDAP Technomed, Inc. The proposed Indication for Use for the Ablatherm Integrated Imaging device, as stated in the PMA, is as follows:

The Ablatherm Integrated Imaging device is intended for the primary treatment of prostate cancer in subjects with low risk, localized prostate cancer.

On July 31, 2014, the committee will discuss and make recommendations regarding the classification of Penile Tumescence Monitors, Nephrostomy Catheters, Stimulators for Electrical Sperm Collection, Erectile Dysfunction Devices, and Alloplastic Spermatocoeles. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Penile Tumescence Monitors are currently regulated under the heading, "Monitor, Penile Tumescence," Product Code LIL, as unclassified under the 510(k) premarket notification authority. Nephrostomy Catheters are currently regulated under the heading, "Catheter, Nephrostomy," Product Code LJE, as unclassified under the 510(k) premarket notification authority. Stimulators for Electrical Sperm Collection are currently regulated under the heading, "Stimulator, Electrical for Sperm Collection," Product Code LNL, as unclassified under the 510(k) premarket notification authority. Erectile Dysfunction Devices are currently regulated under the heading, "Device, Erectile Dysfunction," Product Code LST, as unclassified under the 510(k) premarket notification authority. Alloplastic Spermatocoeles are currently regulated under the heading, "Spermatocoele, Alloplastic," Product Code LQS, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the safety and effectiveness and the regulatory classification of Penile Tumescence Monitors, Nephrostomy Catheters, Stimulators for Electrical Sperm Collection, Erectile Dysfunction Devices, and Alloplastic Spermatocoeles.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee

meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 24, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 30, 2014, and between approximately 8:50 a.m. and 9:50 a.m. on July 31, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 16, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 17, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark at [James.Clark@fda.hhs.gov](mailto:James.Clark@fda.hhs.gov), or 301-796-5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).